



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	INVENTOR	ATTORNEY DOCKET NO.
	07/27/98	TOVEY, FIRST NAMED INVENTOR	23164-1001

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EXAMINER
GOLDBERG, J

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/27/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/853,870**

Applicant(s)  
**Yovey**

Examiner  
**Jerome D. Goldberg**

Group Art Unit  
**1614**



☒ Responsive to communication(s) filed on Jan. 26, and Apr. 27, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) 1-5, 7-12, and 14-16 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 6, 13, and 17-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claims 1-5, 7-12, and 14-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Samo et al. reference of record.

The Samo et al reference teaches a dose of  $40 \times 10^6$  units of interferon (see page 181, col. 1, line 5 after Abstract). In view of this, Applicant's claimed composition would be motivated.

Claims 6, 13 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Cummins Jr. patent of record.

The Cummins, Jr. patent teaches interferon being administered by the oral mucosa at  $51 \text{ } \mu\text{g}$  per day for treating neoplastic disease (col. 4, lines 54-64). In view of this, applicant's claimed methods and composition for treating neoplastic disease would be motivated in the absence of a side-by-side comparison.

Claims 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the neoplastic conditions disclosed (see page 10), does not

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reasonably provide enablement for the term “neoplastic condition”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term “neoplastic conditions” in claims 6 and 13 lacks clear exemplary support in the specification as filed. The cancer therapy art remains highly unpredictable, and no example exists for efficacy of a single product against neoplasms generally. Therefore, based on the unpredictable nature of the invention and state of the art, the lack of guidance and working examples, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation. Changing the term to “neoplastic condition sensitive to interferon” would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday from 9:00 a.m. to 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintinis, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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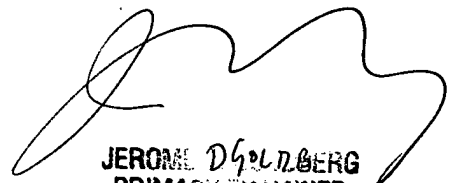
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

✓

J. Goldberg:jmr

July 17, 1998



JEROME D. GOLDBERG  
PRIMARY EXAMINER  
GROUP 1200